

Notice of Allowability

Application No.

10/748,572

Examiner

Eric S. Olson

Applicant(s)

BORGES, RICHARD B.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's communication submitted August 9, 2006.
2. ☒ The allowed claim(s) is/are 1, 2, 4, 5, 6, 8, 10-13, 20, 21, and 23-29, herein renumbered 1-19 respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

SHAOJIA ANNA JIANG, PH.D.
SUPERVISORY PATENT EXAMINER

Detailed Action

This application claims benefit of provisional application 60/437104, filed December 30, 2002. Applicant's amendment, submitted August 9, 2006 is acknowledged wherein claims 1, 2, 5, 6, 8, 9, 12, and 13 are amended, claims 3, 7, and 14-19 are cancelled, and new claims 20-29 are introduced.

Claims 1, 2, 4-6, 8-13, and 20-29 are pending in this application and examined on the merits herein.

Applicants' petition to correct inventorship, filed September 2, 2005, adding Scott A. Shapiro as a joint inventor, accompanying the Inventor's declaration and power of attorney, has been accepted and approved. Accordingly, this application has been corrected in compliance with 37 CFR 1.48(1). The inventorship of this application has been changed by the addition of Scott A. Shapiro as a joint inventor.

The reasons for allowance will be discussed below.

The reasons for allowance and Examiner's amendment are as follows:

Examiner's Amendment

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Homer Faucett on October 19, 2006.

The title of the invention is amended as follows:

Method of treatment for ~~central nervous system~~ spinal cord injury.

The abstract is amended as follows:

Injuries to the ~~central nervous system~~, particularly spinal cord injuries, which are over 100 hours old are treated by administering a purine nucleoside ~~or analog~~ to the patient and, ~~optionally~~, additionally electrically stimulating the site of injury.

Claims 1, 9, 13, and 22 are amended as follows:

1. (Amended) A method for treating a patient having a spinal cord injury, this method comprising:

electrically stimulating the site of the spinal cord injury through the use of oscillating field stimulation; and

administering a purine nucleoside to the patient;

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wherein nerve function through said injured spinal cord is at least partially restored;

wherein the spinal cord injury occurred at least 100 hours prior to the combination treatment.

9. (Cancelled)

13. (Amended) A method for treating a patient having a spinal cord injury, this method comprising:

electrically stimulating the site of a chronic spinal cord injury through the use of oscillating field stimulation; and

administering a purine nucleoside to the patient;

wherein nerve regeneration at the site of the chronic spinal cord injury is stimulated;

wherein the spinal cord injury occurred at least 100 hours prior to the combination treatment.

22. (Cancelled)

23. (Amended) The method of claim ~~22~~13, wherein the step of electrically stimulating the site of a chronic injury occurs more than three weeks after the spinal cord injury occurs.

Reasons for Allowance

Currently, claims 1, 2, 4-6, 8, 10-13, 20, 21, and 23-29, are pending in this application.

Claims 1, 2, 4-6, 8, 10-13, 20, 21, and 23-29, have been examined on the merits herein.

The claimed method of treating a spinal cord injury by the combined administration of oscillating field stimulation and a purine nucleoside, wherein the spinal cord injury is more than 100 hours old, is not seen to be taught or fairly suggested by the prior art, and is directed towards adequately described and enabled by Applicant's specification, as discussed below.

For example, the guinea pig model of spinal cord injury and regeneration disclosed on pp. 17-29 of the specification provides adequate written description and enablement for the claimed invention. One skilled in the art would be able to practice the claimed invention without performing undue experimentation. Furthermore, the prior art teaches no methods by which spinal cord injuries older than 100 hours may be successfully treated by oscillating field stimulation, administration of purine nucleosides, or a combination of the two.

Applicant's amendment, submitted August 9, 2006, with respect to the rejection of instant claims 14-15 under 35 USC 102 in view of Benowitz, (of record in the prior office action) has been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer pending.

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Applicant's amendment, submitted August 9, 2006, with respect to the rejection of instant claims 14-15 under 35 USC 102 in view of Baranowitz, (of record in the prior office action) has been fully considered and found to be persuasive to remove the rejection as the rejected claims are no longer pending.

Applicant's arguments, submitted August 9, 2006, with respect to the rejection of claims 1-4, 7-8, 10-13, and 16-19 over Benowitz in view of Borgens et al. (of record in the previous office action) has been fully considered and is deemed to be sufficient to overcome the rejection under 35 USC 103 as the declaration filed under 37 CFR 1.132 demonstrates that the prior art does not teach every limitation of the claimed invention.

Although the prior art does teach both individual components of this method separately for the treatment of injuries less than 100 hours old, these methods are both ineffective individually when applied to injuries over 100 hours old, as stated in the declaration. (paragraphs 8 and 9. The prior art does not disclose that, when combined, these two methods possess the additional feature of being able to treat spinal cord injuries older than 100 hours, as demonstrated by the animal experiments on pp. 17-29 of the instant specification. Therefore the insertion of the limitation, **"wherein the spinal cord injury occurred at least 100 hours prior to the combination treatment,"** into all independent claims renders the claims patentable over the prior art. Therefore the rejection is withdrawn.

Applicant's arguments, submitted August 9, 2006, with respect to the rejection of claims 1-3, 5-7, 9-13, and 16-19 under 35 USC 103 over Baranowitz in view of Borgens et al. (of record in the previous office action) has been fully considered and is deemed to be sufficient to overcome the rejection under 35 USC 103 as the declaration filed under 37 CFR 1.132 demonstrates that a method of producing additional neurons through transdifferentiation would not be useful for the treatment of spinal cord injuries. In particular paragraphs 3-6 disclose that paralytic spinal cord injuries involve the destruction of spinal cord white matter, which contains axons but no cell bodies. Thus, as described in paragraph 6 of the declaration, one of ordinary skill in the art would not expect the method of Baranowitz to lead to any regeneration of white matter, as opposed to gray matter. Therefore the method of Baranowitz would not be expected to exert any recovery of nerve function through an injured spinal cord. Therefore this rejection is withdrawn.

In view of the information discussed above, the indicated subject matter is allowable over the prior art.

Accordingly, Applicant's amendment submitted August 9, 2006, the rule 132 declaration submitted October 13, 2006, and the accompanying examiner's amendment, are sufficient to remove all rejections made in the prior office action as discussed above and to place the application in condition for allowance.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably

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accompany the issue fee. Such submissions should be clearly labeled, "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday-Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571)272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Eric Olson

A handwritten signature in black ink, appearing to read "Eric S. Olson".

Patent Examiner

AU 1623

10/17/06

Anna Jiang

A handwritten signature in black ink, appearing to read "SA 10/27/06".

Supervisory Patent Examiner

AU 1623